DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 15, 2014

The Procter & Gamble Company
Dr. Michael A. Kaminski
Regulatory Affairs Manager
1 Procter & Gamble Plaza
Cincinnati, Ohio 45202

Re: K141018
Trade/Device Name: Oral-B® Test Drive Power Brush Trial Program Kit
Regulation Number: 21 CFR 872.6865
Regulation Name: Toothbrush, Powered
Regulatory Class: I
Product Code: JEQ
Dated: August 14, 2014
Received: August 15, 2014

Dear Dr. Kaminski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): To Be Assigned

Device Name: Oral-B® Test Drive Power Brush Trial Program Kit

Indications for Use:
The Oral-B® Test Drive Power Brush Trial Program Kit is intended for use as a power toothbrush to promote good oral hygiene, including the reduction of dental plaque and the treatment and prevention of gingivitis.

The Oral-B® Test Drive Power Brush Trial Program Kit is indicated for use under the supervision of a dental professional as part of the Oral-B® Test Drive Power Brush Trial Program.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

5. 510(k) Summary

510(k) Submission, Traditional; as required by (21CFR§807.92(c))

510(k) Owner: The Procter & Gamble Company
1 Procter & Gamble Plaza
Cincinnati, Ohio 45202
Telephone: (513) 622-2879 (Attention: Michael A. Kaminski)
Facsimile: (513) 277-8009 (Attention: Michael A. Kaminski)
Establishment Registration Number: 9915005

Contact Person: Michael A. Kaminski, Ph.D.
Regulatory Affairs Manager
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The Procter & Gamble Company

Telephone: (513) 622-2879
Email: kaminski.ma@pg.com
Facsimile: (513) 277-8009

Date: August 14, 2014

Trade Name: Oral-B® Test Drive Power Brush Trial Program Kit

Common name: Power Toothbrush

Classification Name: Toothbrush, Powered

Product Code: JEQ

Identification of a Legally Marketed Predicate Device
The Oral-B® Test Drive Power Brush Trial Program Kit ("program kit") is substantially equivalent to the Oral-B® Rechargeable Toothbrush marketed by Procter & Gamble, 510(k) Premarket Notification Number: K061199, FDA Product Code JEQ (Class I, 510(k) Exempt).

General Description
The Oral-B® Test Drive Power Brush Trial Program is designed to introduce potential users to a power toothbrush as a means to promote good oral hygiene, including the reduction of dental plaque and the treatment and prevention of gingivitis. The program kit that is used in the trial program contains a power toothbrush consisting of a rechargeable handle, charger, replacement brush heads, and instructions for the proper use and care of the device. Additionally, the program kit contains plastic dental sheaths to prevent soiling of the multi-user handle and

instructions for cleaning and disinfection of the reusable handle. The program kit is indicated for use as an introductory trial to a power toothbrush under the supervision of a dental professional as part of the Oral-B® Test Drive Power Brush Trial Program.

Intended Use/Indications for Use
The Oral-B® Test Drive Power Brush Trial Program Kit is intended for use as a power toothbrush to promote good oral hygiene, including the reduction of dental plaque and the treatment and prevention of gingivitis.

The Oral-B® Test Drive Power Brush Trial Program Kit is indicated for use under the supervision of a dental professional as part of the Oral-B® Test Drive Power Brush Trial Program.

Comparison of Technological Characteristics
The Oral-B® Test Drive Power Brush Trial Program Kit is substantially equivalent to the Oral-B® Rechargeable Toothbrush (K061199) in intended use, design, dimensions, material biocompatibility and performance. The program kit differs from the Oral-B® Test Rechargeable Toothbrush device with regards to the cleaning and disinfection instructions for the handle to permit multiple-users of the reusable handle. The program kit and the Oral-B® Rechargeable Toothbrush are both manufactured by Procter & Gamble Manufacturing GmbH (Marktheidenfeld, Germany) and distributed in the U.S.A. by Procter & Gamble, Co. (Cincinnati, Ohio).

Brief Summary of Non-Clinical Tests and Results
Benchtop testing for the program kit was performed under conditions that simulated normal use and worst case scenario for wear. The performance testing demonstrated that the program kit handle can sustain multiple fittings of the brush head onto the reusable handle, and that the integrity of the seal remains intact with normal use. Benchtop testing also demonstrates that the cleaning and disinfection procedure results in satisfactory disinfection of the handle, and that the repeated exposure of the handle to the disinfectant had no effect on the physical characteristics or performance of the device.

Basis of Substantial Equivalence
The Oral-B® Test Drive Power Brush Trial Program Kit is substantially equivalent to the Oral-B® Rechargeable Toothbrush in intended use, design, dimensions, materials, biocompatibility, and performance.

Accessory Device
The Oral-B® Sheath, manufactured by TIDI Products, LLC, is provided to Procter & Gamble as a finished, packaged non-sterile device for inclusion in the program kit as an accessory device.